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09/621,565	07/21/2000	Miri Seiberg	JBP0510	4999

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,565

Applicant(s)

SEIBERG ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 May 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24,26,27 6) Other:

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 filed 05/12/03 and prior art filed 02/28/03, 05/12/03 and 05/20/03. Claims 1-22 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on 05/12/03 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for soymilk, does not reasonably provide enablement for all leguminosae family. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these

Art Unit: 1615

claims. The specification enables extract from soy and not from all members from the legume family. In fact no mention is made of any other member from the legume family.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not contain description of compounds extracted form the solanaceae, gramineae and cucurbitacea families. In fact there is no mention of solanaceae, gramineae and cucurbitacea families in the written disclosure.

5. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing pseudofolliculitis barbae, does not reasonably provide enablement for preventing pseudofolliculitis barbae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no correlating data in applicants' specification showing prevention of said condition of pseudofolliculitis barbae..

For rejections under 35 U.S.C. 112, first paragraph, the following factors are considered

(In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.

Art Unit: 1615

6) Existence of working examples

7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1. Nature of the invention:

The claims are drawn to method for effecting changes in mammalian hair appearance and hair pigmentation and reducing hair growth with extract from leguminosae, solanaceae, gramineae and cucurbitaceae. Applicants' specification discusses soymilk only and no mention is made of other members of the legume family, and no mention is made of extracts from solanaceae, gramineae and cucurbitaceae families.

2. State of the prior art:

The prior art does not disclose that all extracts from the leguminosae, solanaceae, gramineae and cucurbitaceae families may be useful in the instant method of reducing hair growth, hair follicle and hair shaft size.

3. Level of Ordinary Skill in the art:

The level of ordinary skill in the art is high. Applicants' specification does not enable the public to use extracts from all leguminosae, solanaceae, gramineae and cucurbitaceae families of plants other than soymilk.

4. Level of predictability:

Since applicants' specification discloses extract from soy and not from other members of the legume family or from the solanaceae, gramineae and cucurbitaceae families, the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention would have little predictability. The lower the predictability, the higher the direction and guidance that

Art Unit: 1615

must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants.

5. Amount of direction and guidance provided by the inventors:

The amount of direction and guidance provided by the applicants is limited to soymilk. There is no evidence in the specification that established correlation between soymilk and all the other extracts from leguminosae, solanaceae, gramineae and cucurbitacea families. See Ex parte Mass, 9 USPQ2d 1746, 1987.

6. Existence of working examples:

Applicants' specification exemplifies topical treatment of skin with soymilk and disclosure makes no mention of extracts from other plant families of leguminosae, solanaceae, gramineae and cucurbitacea.

7. Quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The quantity of experimentation required to use the invention as claimed, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experimentation with extracts from numerous plants from the leguminosae, solanaceae, gramineae and cucurbitacea families to determine those that will work in the invention and those that would not work.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1615

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 6, 7, 9, 15 and 19 rejected under 35 U.S.C. 102(e) as being anticipated by Costanzo (US 6,323,219).

Costanzo discloses topically applying pharmaceutical or cosmetic composition in an amount effective to mammalian skin to effect changes in pigmentation (column 10, lines 13-17) and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin (column 9, lines 47-52). Costanzo discloses that extracts from the plant families of leguminosae, solanaceae, gramineae and cucurbitacea contain serine protease inhibitors (column 8, lines 52-57). The teaching of Costanzo meets the limitations of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 5, 8, 10-14, 16-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219) in view of JP 9059166 A.

Art Unit: 1615

The teachings of Costanzo is discussed above and Costanzo discloses the method of the instant claims. Regarding claims 4 and 5, there is no showing demonstrating that the amount of the inhibitor provides unusual results. Regarding claims 11-14, 16-18 and 20-22, since the composition of the prior art is applied to the skin, the composition would exhibit the properties of the composition on the skin.

Costanzo does not teach that the composition comprising the plant extracts contains isoflavones. However, JP 9059166 discloses that soybean extract contains isoflavones (English abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the extract of soy bean to apply to the skin in order to effect changes in mammalian hair appearance. One having ordinary skill in the art would have been motivated to include isoflavone in the composition of Costanzo with the expectation that the composition produce changes in the mammalian hair appearance.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Application/Control Number: 09/621,565

Page 8

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
August 10, 2003

MB Fubara